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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,052	02/06/2004	Kurt Berlin	81587CIP	4830
23685 7590 10/17/2007 KRIEGSMAN & KRIEGSMAN 30 TURNPIKE ROAD, SUITE 9 SOUTHBOROUGH, MA 01772			EXAMINER CLOW, LORI A	
			ART UNIT 1631	PAPER NUMBER
			MAIL DATE 10/17/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/774,052

Applicant(s)

BERLIN ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 6, 16, 17 and 20-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 6, 16, 17, and 20-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 27 July 2007, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 2, 6, 16, 17, and 20-22 are currently pending. Claims 1, 2-5, 7-15, 18, 19, and 23-50 have been cancelled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 2 and 6 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. With respect to claims 2 and 6 Applicant argues that the claims fulfill a long-felt need by medical practitioners for standardized systems of storing and organizing molecular diagnostic information to enable accurate means of both diagnosing patient disease and recommending appropriate treatments.

This is not persuasive. As was stated previously in the Office Action of 23 January 2007, claims 2 and 6 are directed to a method for guiding selection of a therapeutic treatment regimen comprising steps of providing information about methylation of DNA of a patient and generating

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a ranked list of diseases based on the methylation and knowledge base based on expert rules for evaluating and selecting a type of disease based on methylation status of DNA of a patient. The claims further recite steps of generating, **in the computing device**, advisory information and accessing information via the computer device.

However, not all processes are statutory under 35 U.S.C. 101. See MPEP 2106 (Section IV in particular). To satisfy 101 requirements, the claim must be for a practical application, which can be met if the claimed invention "transforms" an article or physical object to a different state or thing **OR** the claimed invention otherwise produces a useful, concrete, and tangible result. If claims are directed to abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature, the claims must be considered as a whole for determining whether an abstract ideas, natural phenomena, or laws of nature has a particular application. In the instant case, the claimed method steps describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic 'abstract idea.' MPEP 2106 Section IV. Specifically, the claimed method recites mathematical and/or statistical manipulations with methylation information. The claimed method does not transform or reduce an article or a physical object (e.g., methylated DNA) to a different stage or thing because the "result" of the method (i.e., generated ranked list of diseases; ranked therapeutic treatment regimens, advisory information) is merely data (information) and is not equivalent to physical transformation.

As the claims do not provide for a physical transformation of data, the claims must be evaluated for providing a concrete, tangible, and useful result. In the instant case, the claims do not recite tangible expression (i.e., real-world result) of generated ranking or advisory information, nor any recitation of an actual (i.e., concrete) result in a form useful to one skilled in

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the art. Thus, the method does not recite steps of producing something that is concrete, useful, and tangible, and is not statutory. Merely generating, in a computer device, a ranked list, does not provide for the result to be realized in tangible form, for instance, to a user. Therefore the rejection is maintained for claims 2 and 6.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 6, 16, 17, and 20-22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues that the Patent Office has failed to prove that the amount of experimentation that is required is "undue".

This is not persuasive. The previous Office Action of 23 January 2007 clearly sets forth an analysis of why, indeed, the instant claims lack enablement. The proper analysis of this is set forth in *In re Wands* (*In re Wands*, 858 F.2d 731,737 (Fed. Cir. 1988), of which was properly and clearly applied in the previous Office Action to illustrate the lack of enablement of the instant

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claims. Applicant has provided no evidence to the contrary that the instant claims are enabled and therefore, the claims remain rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 6, 16, 17, and 20-22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the previous Office Action.

Response to Applicant's Arguments

1. Applicant argues that the claims in question are definite.

This is not persuasive. Applicant has provided no explanation as to why the claims are now definite or any support from the specification illustrating why the claim may be definite. Further, the amendments to the claims were simply made by incorporating limitations from dependent claims. However, claim language has not been altered and the outstanding rejections to the claims under 112, 2nd paragraph still apply.

Double Patenting

Claims 2, 16, and 17 remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 4, 5, 8, and 28 of copending Application No. 10/857,105.

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This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

The outstanding double patenting rejections over claims 6 and 20-22 have been withdrawn in view of the claim amendments.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

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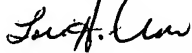
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

LORI A. CLOW, PH.D.
PRIMARY EXAMINER



October 12, 2007

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